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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,099	10/31/2003	Dale B. Schenk	015270-006930US	7805

20350 7590 06/10/2009

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,099	SCHENK ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9-13,54 and 55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 9-13 and 54-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/23/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 2/24/2009. The status of the claims is as follows: claims 1, 3-6, 9-13 and 54-55 are pending and under current examination and claims 2, 7-8 and 14-53 are cancelled.

Information Disclosure Statement

The IDS filed 1/23/2009 was considered in its entirety and an initialed copy is attached.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9-13 and 54-55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda (PNAS, 1993) in view of US Patent Nos. 6416947,

5583112 and 6172122 for reasons of record as set forth in the action mailed 10/24/2008.

Response to Arguments

Applicant's arguments filed 2/24/2009 have been fully considered but they are not persuasive.

Applicant submits that the Ueda reference is silent as to which adjuvant is used and provides that "it can be conclusively determined that the adjuvant was Freund's adjuvant" based upon overlapping authorship and procedures with a separate reference by Yoshimoto and Wakabyashi (Remarks, p. 4). Note that such limitations cannot be read into a published reference. Separately, the argument is not on point. Whether Ueda discloses the use of adjuvants *or not*, such use is well-described in the prior art, including within the cited art (see '697 patent).

It is noted Applicant *acknowledges* that Ueda teaches a NAC peptide (Remarks, p. 4, see instant claims 5 and 13) and Applicant further notes that this peptide was used for antibody production, meeting the claim limitation of "effective to elicit an immunogenic response" of instant claims 1 and 9 (Remarks, p. 5).

With respect to the '697 patent, Applicant contends that this patent discusses the differential potencies of various adjuvants and that "poloxamer was found to be more immunogenic than alum and Quil A and possibly more immunogenic than Ribi O/W" (Remarks, p. 5). Applicant states that "the '697 patent does not provide any evidence that alum and lipid A are more potent than its polyoxamer or Freund's adjuvant" (Remarks, p. 6). In response, nonpreferred and alternative embodiments still constitute

prior art (see MPEP 2123, also *In re Susi, In re Gurley*). While Applicant contends that other adjuvants may be more potent than alum or Quil A, note that Applicant does not provide any discovery beyond what was known in the art; alum and Quil A are known adjuvants and it is not clear why an adjuvant needs to be more potent than polyoxamer or Freund's adjuvant. It is further noted that this reference was cited in disclosing the claimed adjuvants while the '122 patent was cited for disclosing GMP procedures.

Lastly, Applicant provides that "the case of obviousness assumes that laboratory researchers would voluntarily make a polyclonal antibody as a research reagent under GMP conditions" and this assumption is implausible (Remarks, p. 5). Applicant further provides that the procedures imposed on manufacturers of drugs to ensure purity and safety of patients would appear an unnecessary and onerous burden to the laboratory researcher (Remarks, p. 6). This is not found to be persuasive. As noted in the rejection, the '122 patent provides that following GMP regulations ensures a clean product which is of purity suitable for its intended use and which does not transit biological disease. The researcher would be expected to use a composition of suitable purity in order to determine and characterize the effects of the composition and not that of any foreign substances. Further, the '122 patent provides that GMP procedures also include general requirements on cleanliness of utensils, equipment, facilities etc. It would be expected for the researcher to follow such general requirements and use clean utensils, equipment and facilities. Note that it would be obvious for any researcher to follow GMP procedures as provided by the FDA for any composition expected to be used as therapeutic drug.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648
/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646